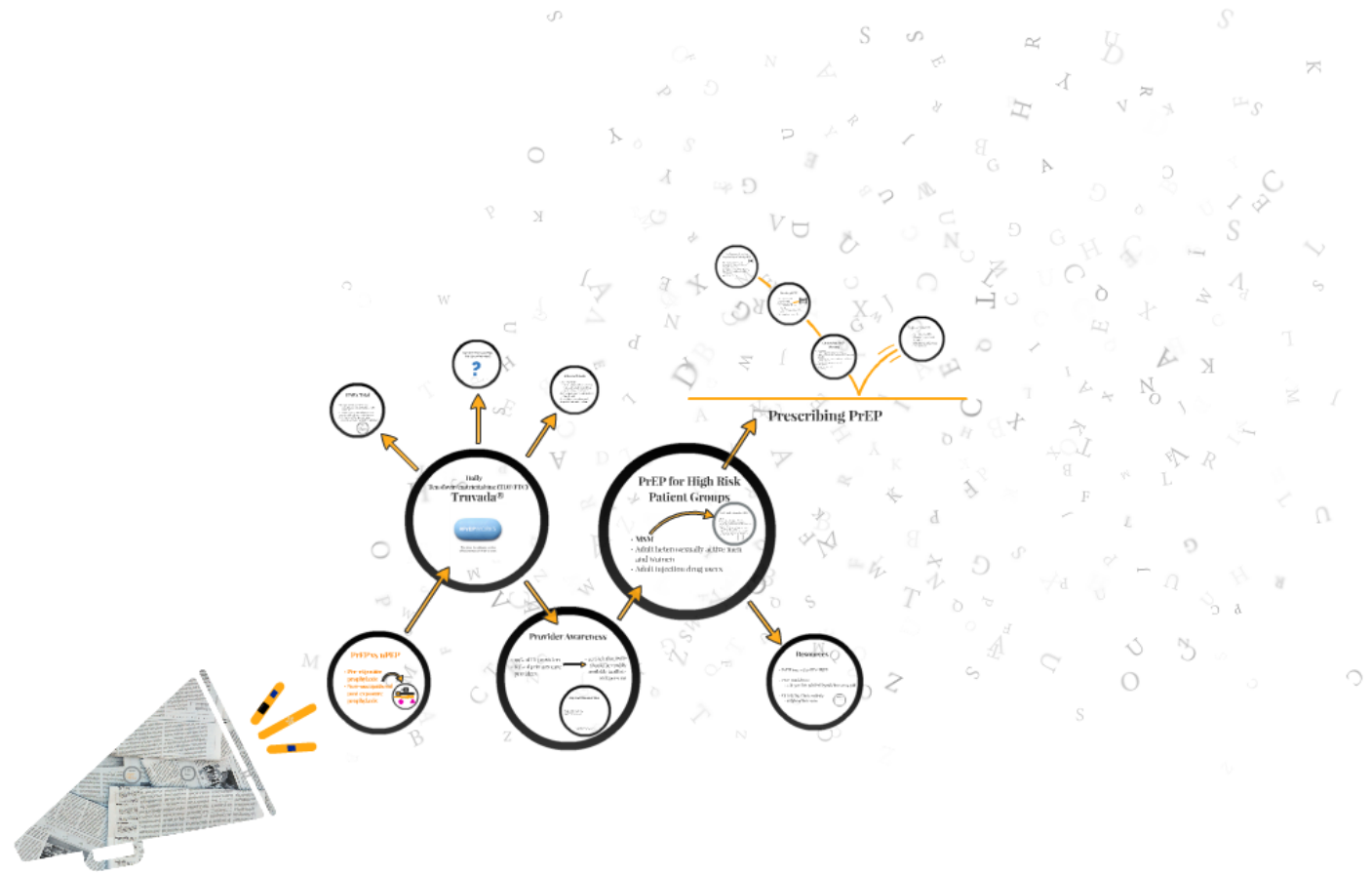


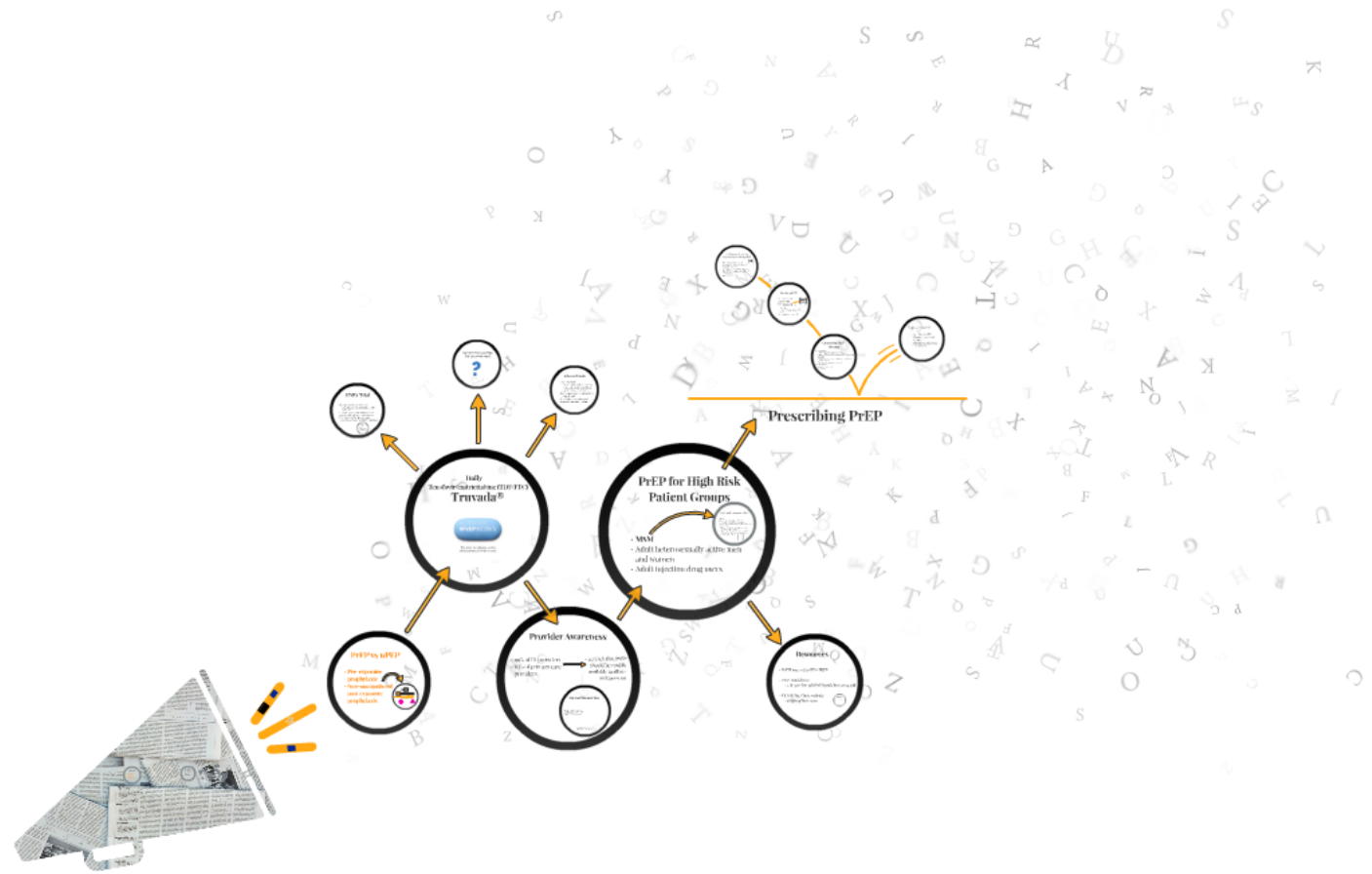
PrEP: The Time is Now!

Katie Imborek, MD



PrEP: The Time is Now!

Katie Imborek, MD



Objectives

- Analyze evidence for PrEP
- Assess MSM for PrEP indications
- Perform initial labs
- Monitor for side effects

Disclosure

- No relevant financial relationships
- Will not discuss any off-label products



UI LGBTQ Clinic

Nationally recognized comprehensive healthcare in a welcoming and affirming environment

[Request An Appointment](#)

Welcome to UI LGBTQ Clinic

[En Español](#)

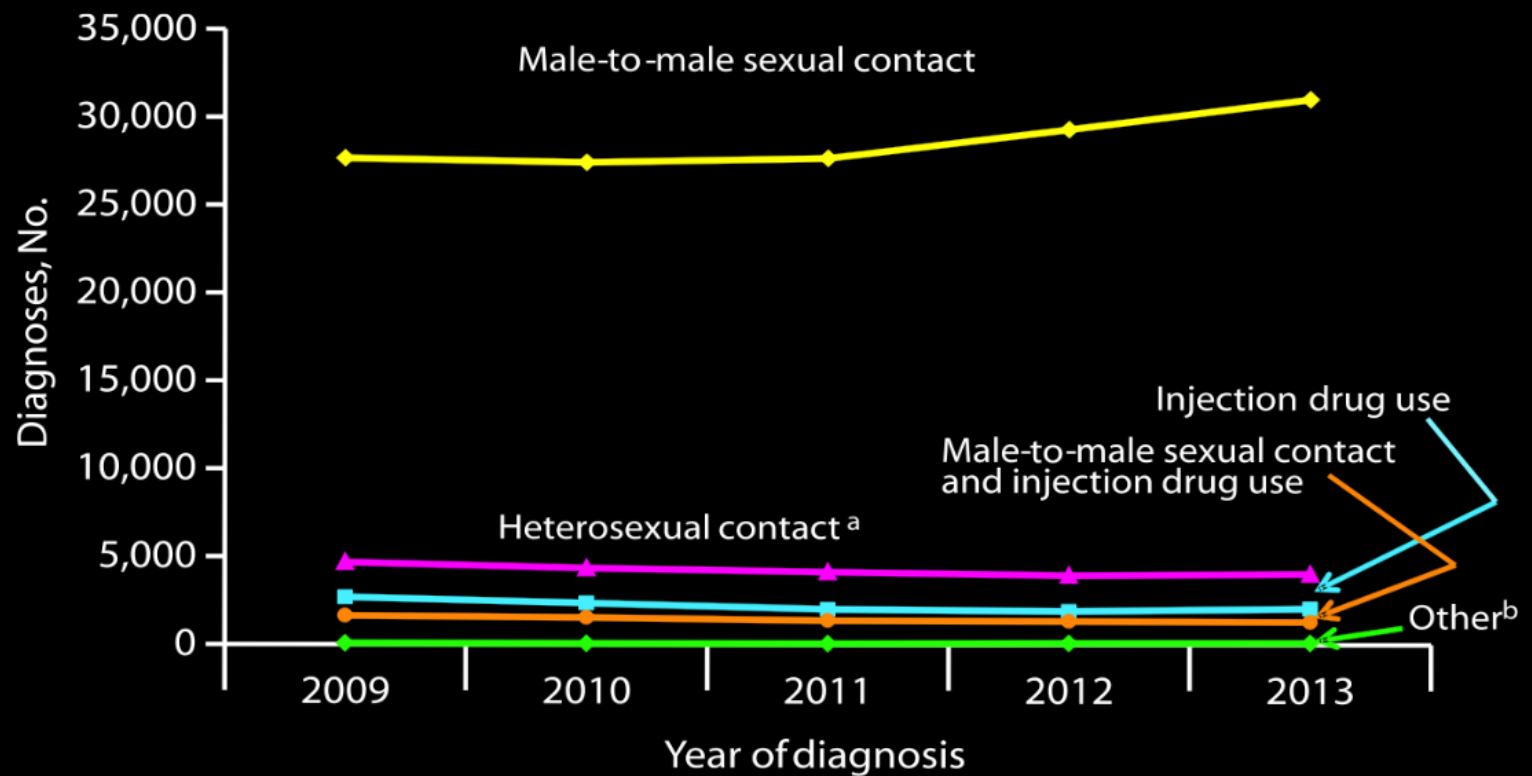
The University of Iowa LGBTQ Clinic serves the lesbian, gay, bisexual, transgender, queer and questioning communities. Our clinic provides full-



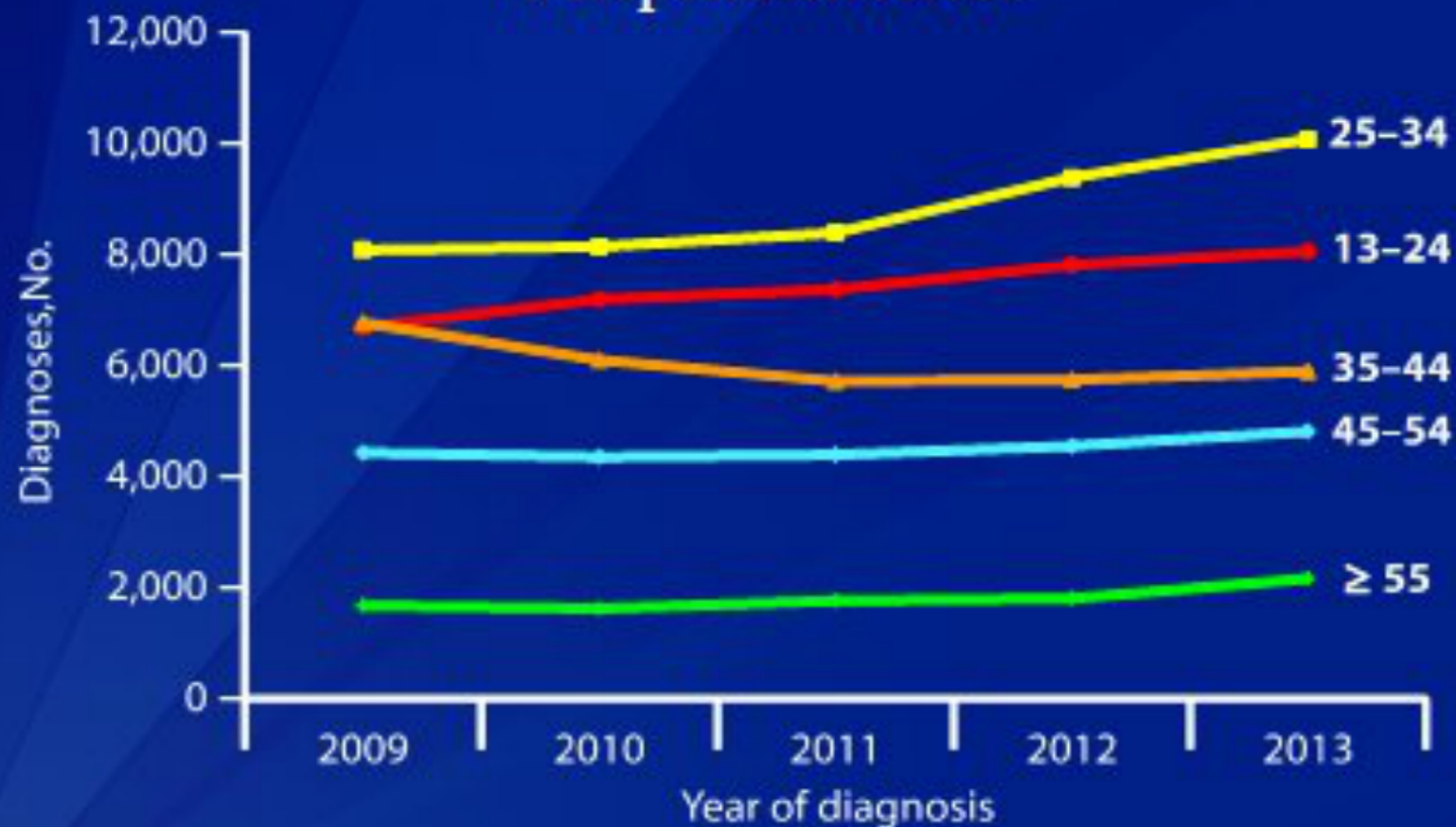
Patient Case

- 25 yo self-identified bisexual man
- Married to a woman
- 2 other non-monogamous male partners
- Penile-vaginal sex with his wife
 - Condom use 0% of the time
- Receptive and insertive anal sex
 - Condom use 90% of the time for each
- Receptive and insertive oral sex
 - Condom use 0% of the time

Diagnoses of HIV Infection among Adult and Adolescent Males, by Transmission Category, 2009–2013, United States and 6 Dependent Areas



Diagnoses of HIV Infection among Men Who Have Sex with Men, by Age Group, 2009–2013—United States and 6 Dependent Areas



Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays and missing transmission category, but not for incomplete reporting. Data on men who have sex with men do not include men with HIV infection attributed to male-to-female sexual contact and injection drug use.



Undiagnosed HIV Infection



Homophobia, stigma, discrimination

Increased Risk Exposure

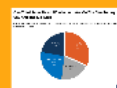


HIV Diagnoses in US

- Adolescent and young adult MSM (13-24 years) saw a **22% increase** in new diagnoses from 2008-2010
- MSM represent 7% of the male population in the US but accounted for 81% of the new HIV infections among males in 2013

<http://www.cdc.gov/hiv/group/msm/>

Low Perception of Risk



More Sex Partners

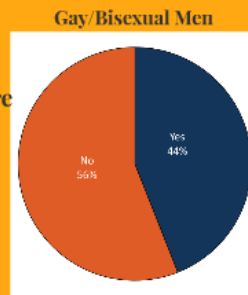
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<http://www.cdc.gov/hiv/group/msm/>

Undiagnosed HIV Infection

Has your health care provider ever recommended that you be tested for HIV?

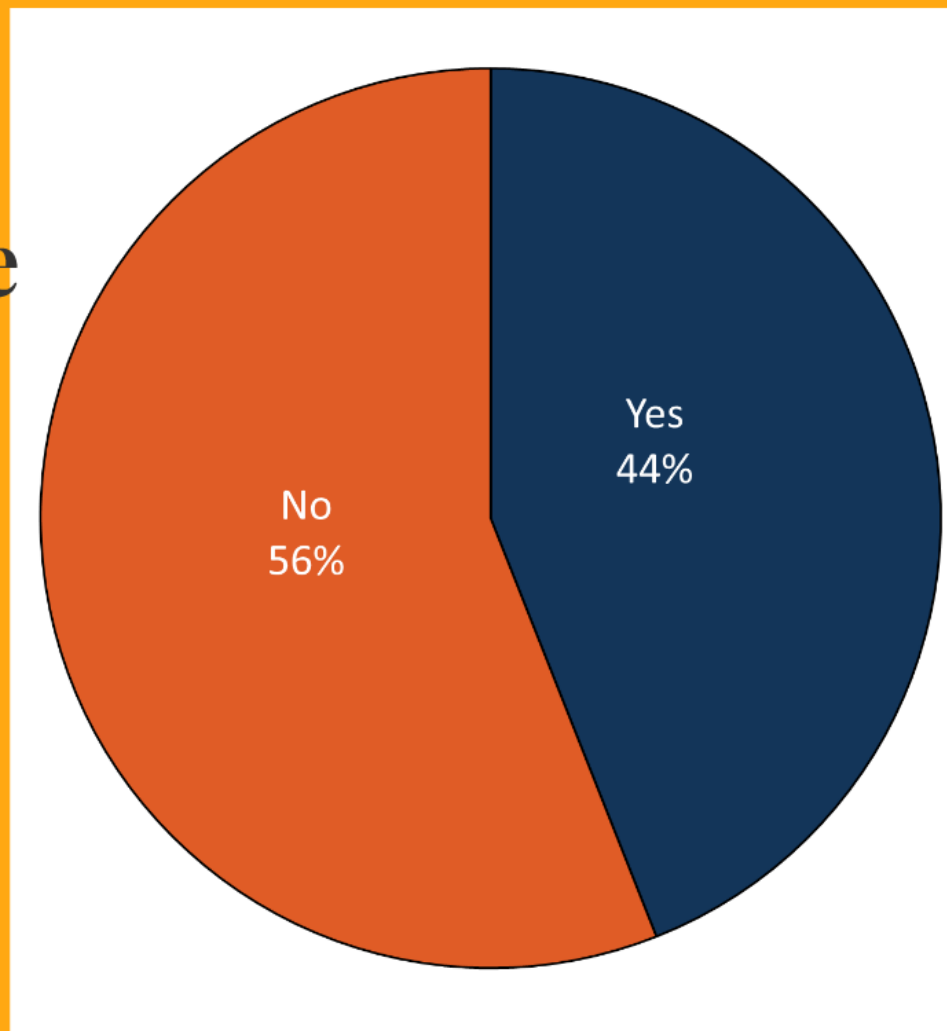


Kaiser Family Foundation Survey on Gay and Bisexual Men on HIV (July–August 2014)



Has your health care provider ever recommended that you be tested for HIV?

Gay/Bisexual Men

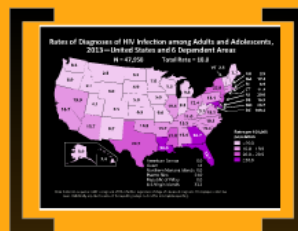


Kaiser Family Foundation Survey on Gay and Bisexual Men on HIV (July-August 2014)



**KEEP
CALM
AND
GET
TESTED**

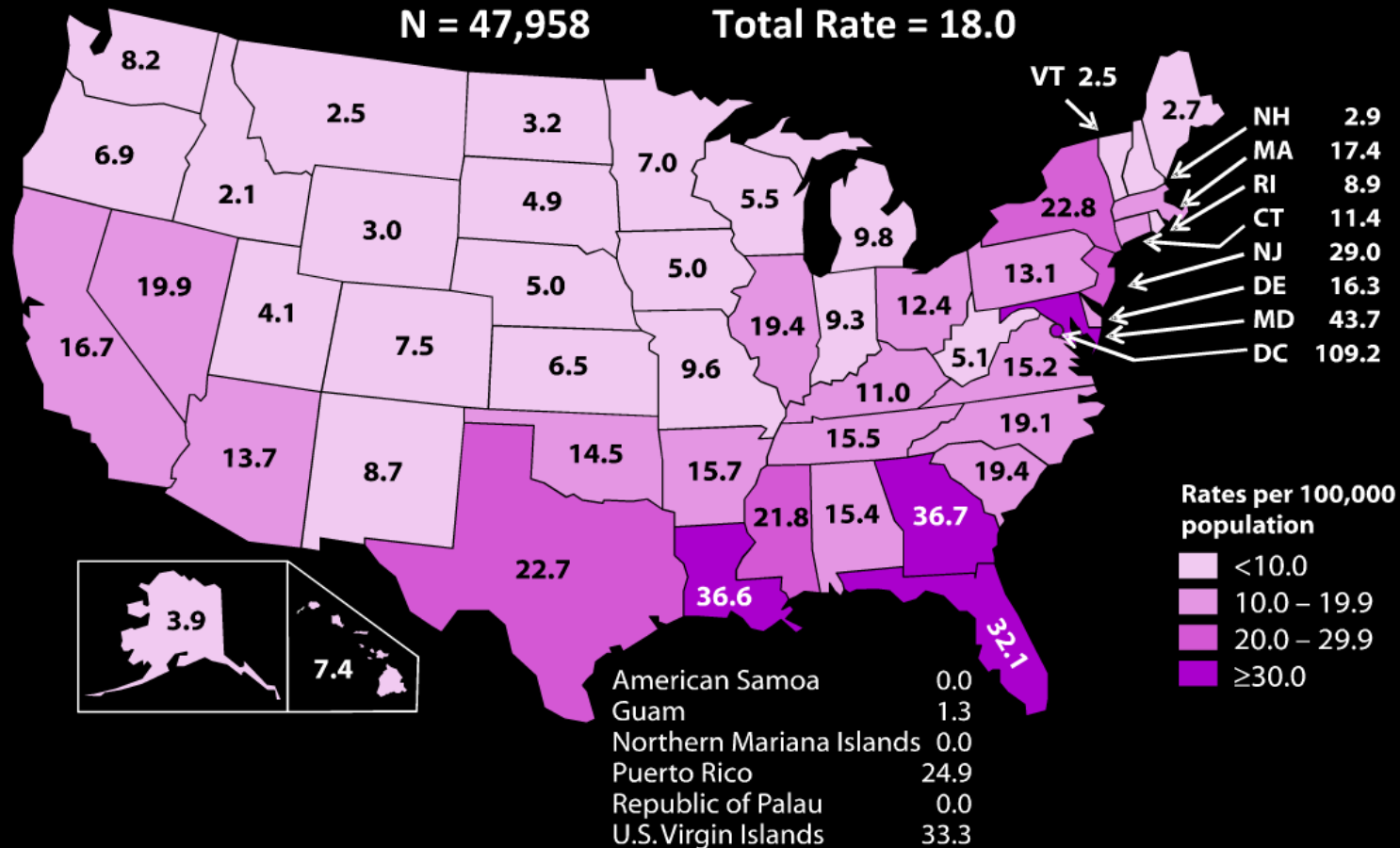
Increased Risk Exposure



Rates of Diagnoses of HIV Infection among Adults and Adolescents, 2013—United States and 6 Dependent Areas

N = 47,958

Total Rate = 18.0



A large black circle is centered on a solid yellow background. The circle's interior is empty, and the text is positioned within this space.

More Sex Partners

Low Perception of Risk

One-Third Know New HIV Infections Are On The Rise Among Gay And Bisexual Men

As far as you know, is the number of new HIV infections each year among gay and bisexual men increasing, decreasing, or staying about the same?

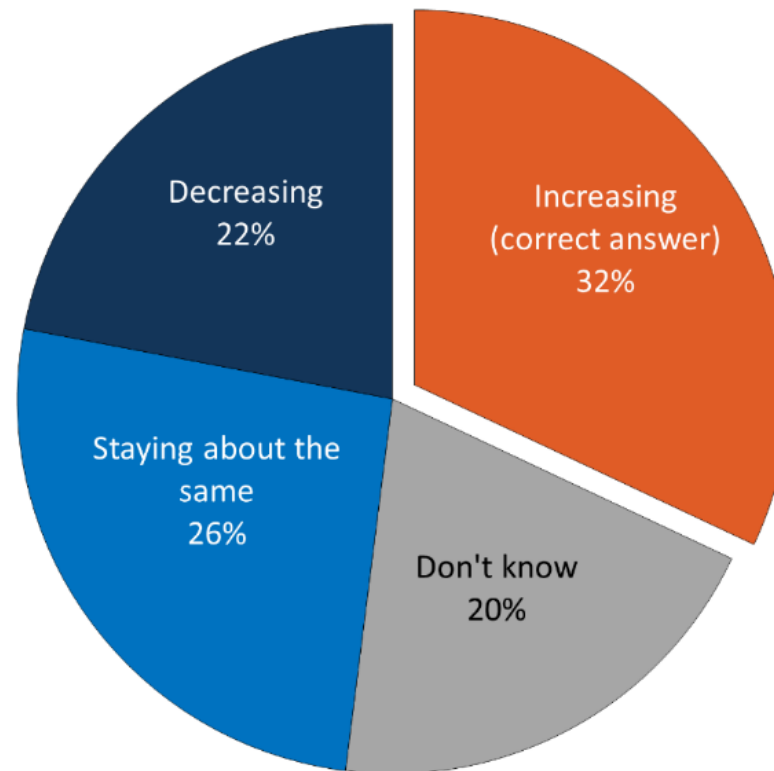


SOURCE: Kaiser Family Foundation Survey of Gay and Bisexual Men on HIV (July 17 - August 3, 2016)



One-Third Know New HIV Infections Are On The Rise Among Gay And Bisexual Men

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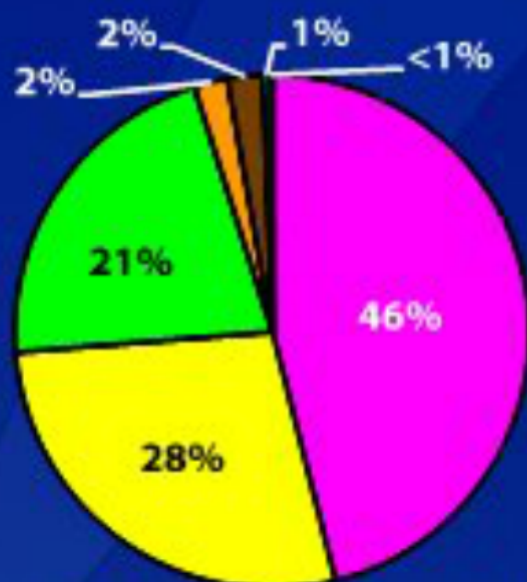
SOURCE: Kaiser Family Foundation Survey of Gay and Bisexual Men on HIV (July 17 - August 3, 2014)

A large black circle is centered on a solid yellow background. Inside the circle, the text "Homophobia, stigma, discrimination" is written in a bold, black, serif font, centered horizontally and vertically.

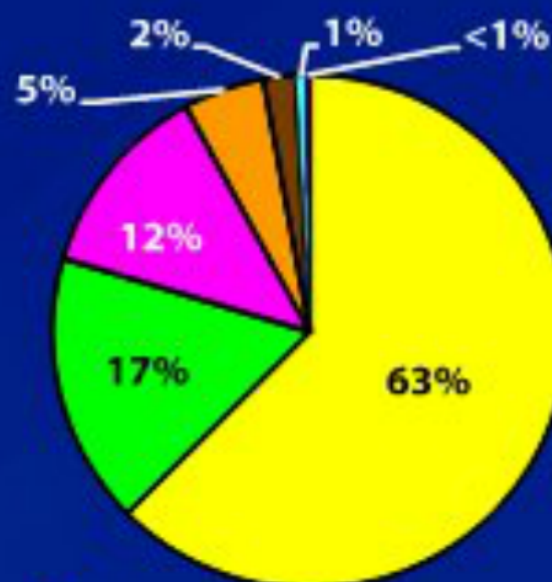
**Homophobia, stigma,
discrimination**

Diagnoses of HIV Infection and Population by Race/Ethnicity, 2013—United States

Diagnoses of HIV infection
N = 47,352



Population, United States
N = 316,128,839



■ American Indian/Alaska Native
■ Asian
■ Black/African American

■ Hispanic/Latino^a
■ Native Hawaiian/other Pacific Islander
■ White

■ Multiple races

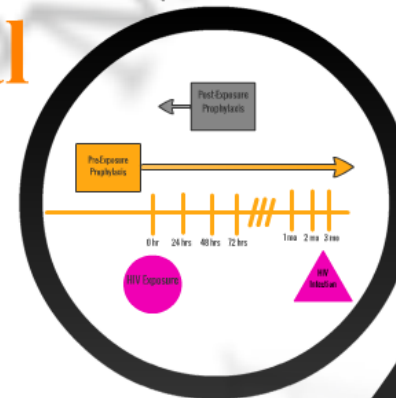
Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease or diagnosis. All displayed data have been statistically adjusted to account for reporting delays, but not for incomplete reporting.

^a Hispanics/Latinos can be of any race.

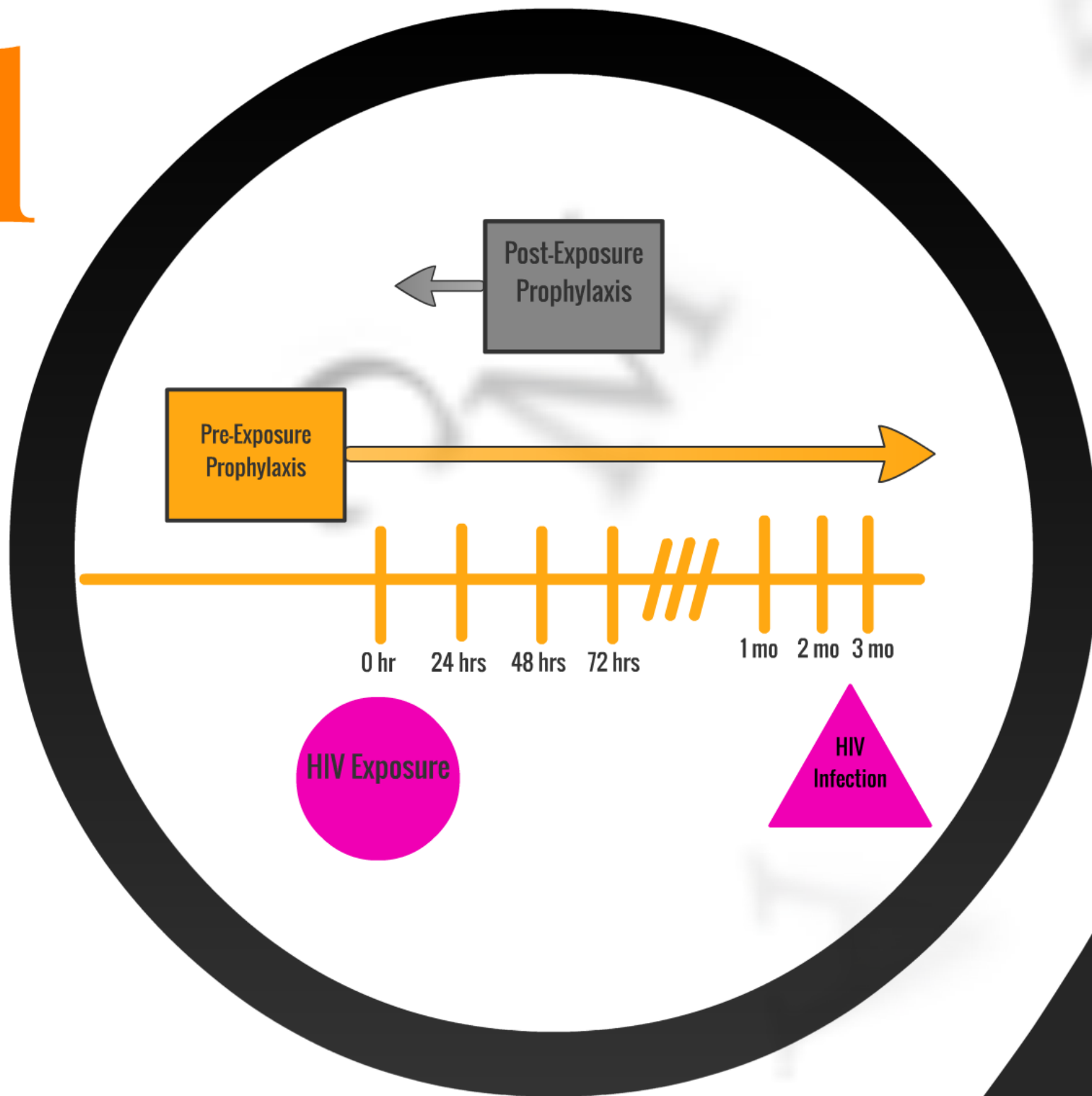


PrEP vs nPEP

- Pre-exposure prophylaxis
- Non-occupational post exposure prophylaxis



mal



**Daily
Tenofovir/emtricitabine (TDF/FTC)
Truvada®**



The time for debate on the
effectiveness of PrEP is over.

iPrEx Trial

- Preexposure Prophylaxis Initiative
 - Peru, Ecuador, Brazil, Thailand, South Africa, US
- 2500 HIV negative MSM and transwomen sexually active with male bodied persons
- Daily fixed dose Truvada vs placebo
 - **Overall 44% reduction in HIV acquisition**

iPrEx Trial

- 97% of patients had Truvada detected in their system
- 92% efficacy
- 99% protection based on modeling drug levels if taken daily
- 100% of iPrEx open label participants did NOT get infected if drug levels were consistent with taking 4 times/week or more



iPrEx Trial

- 51% of patients had Truvada detected in their system
 - **92% efficacy**
- **99% protection** based on modeling drug levels if taken daily
- **100%** of iPrEx open label participants did **NOT get infected** if drug levels with consistent with taking 4 times/week or more

Does PrEP Increase High Risk Sexual Behaviors?



Box B: Key Components of Behavioral Risk-Reduction Counseling

- Establish trust and 2-way communication
- Provide feedback on HIV risk factors identified during sexual and substance use history taking
 - Elicit barriers to, and facilitators of, condom use
 - Elicit barriers to, and facilitators of, reducing substance use
- Support risk-reduction efforts
 - Ask participants directly 1 or 2 specific, acceptable, behavioral steps toward risk reduction
 - Identify and address existing barriers to accomplishing planned actions to reduce risk
- Monitor behavioral adherence in a non-judgmental manner
 - Acknowledge when effort required for behavior change
 - Reinforce success
 - If not fully successful, assess barriers, brainstorm with participant of planned actions and solicit partner to identify next steps

<http://www.cdc.gov/hiv/pdf/PrEPguidelines2014.pdf>

Box E: Key Components of Behavioral Risk-Reduction Counseling

Establish trust and 2-way communication

Provide feedback on HIV risk factors identified during sexual and substance use history taking

- Elicit barriers to, and facilitators of, consistent condom use
- Elicit barriers to, and facilitators of, reducing substance abuse

Support risk-reduction efforts

- Assist patient to identify 1 or 2 feasible, acceptable, incremental steps toward risk reduction
- Identify and address anticipated barriers to accomplishing planned actions to reduce risk

Monitor behavioral adherence in a non-judgmental manner

- Acknowledge the effort required for behavior change
- Reinforce success
- If not fully successful, assess factors interfering with completion of planned actions and assist patient to identify next steps

<http://www.cdc.gov/hiv/pdf/PrEPguidelines2014.pdf>

Adverse Effects

- "Start-Up Effect"
 - Most common side effects were nausea, headache, weight loss
 - Most dissipate by 1 month
- Risk for decrease in renal function
 - Usually mild
- Exacerbation of undiagnosed hepatitis B when discontinued

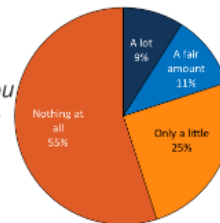
Provider Awareness

- 99% of ID providers
- 83% of primary care providers

- 40% felt that PrEP should be readily available to all at-risk persons

Gay and Bisexual Men

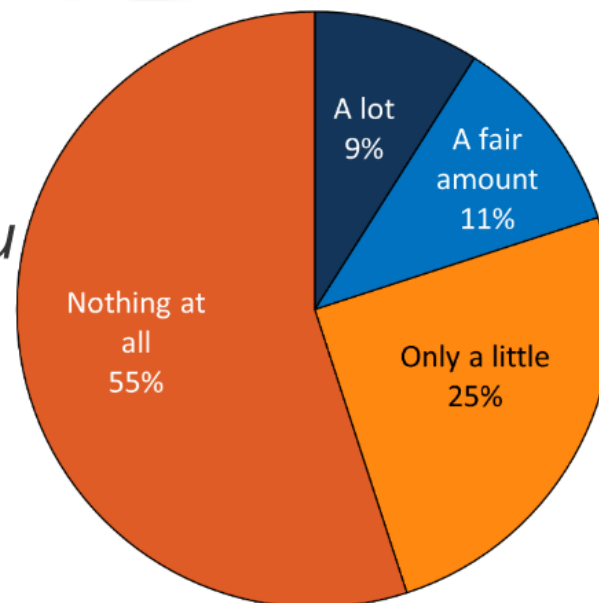
How much have you heard about PrEP?



Kaiser Family Foundation Survey on Gay and Bisexual Men on HIV (July–August 2014)

Gay and Bisexual Men

How much have you heard about PrEP?



Kaiser Family Foundation Survey on Gay and Bisexual Men on HIV (July–August 2014)

PrEP for High Risk Patient Groups

- **MSM**
- Adult heterosexually active men and women
- Adult injection drug users

PrEP Indications for MSM

- Adult man
- Without acute or established HIV infection
- Male sexual partner(s) in the past 6 months
- Not in a monogamous sexual relationship with an HIV negative partner
 - Any anal sex without condoms (receptive or insertive) in past 6 months
 - Diagnosed with an STD in the past 6 months
 - In an ongoing sexual relationship with an HIV-positive male partner



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 - Diagnosed with an STD in the past 6 months
 - In an ongoing sexual relationship with an HIV-positive male partner

1. Name of the patient	2. Date of birth	3. Sex	4. Age
5. Address	6. Phone number	7. Email	8. Occupation
9. Date of last HIV test	10. Date of last STD test	11. Date of last PrEP dose	12. Date of last PrEP dose
13. Date of last PrEP dose	14. Date of last PrEP dose	15. Date of last PrEP dose	16. Date of last PrEP dose
17. Date of last PrEP dose	18. Date of last PrEP dose	19. Date of last PrEP dose	20. Date of last PrEP dose
21. Date of last PrEP dose	22. Date of last PrEP dose	23. Date of last PrEP dose	24. Date of last PrEP dose
25. Date of last PrEP dose	26. Date of last PrEP dose	27. Date of last PrEP dose	28. Date of last PrEP dose
29. Date of last PrEP dose	30. Date of last PrEP dose	31. Date of last PrEP dose	32. Date of last PrEP dose
33. Date of last PrEP dose	34. Date of last PrEP dose	35. Date of last PrEP dose	36. Date of last PrEP dose
37. Date of last PrEP dose	38. Date of last PrEP dose	39. Date of last PrEP dose	40. Date of last PrEP dose
41. Date of last PrEP dose	42. Date of last PrEP dose	43. Date of last PrEP dose	44. Date of last PrEP dose
45. Date of last PrEP dose	46. Date of last PrEP dose	47. Date of last PrEP dose	48. Date of last PrEP dose
49. Date of last PrEP dose	50. Date of last PrEP dose	51. Date of last PrEP dose	52. Date of last PrEP dose
53. Date of last PrEP dose	54. Date of last PrEP dose	55. Date of last PrEP dose	56. Date of last PrEP dose
57. Date of last PrEP dose	58. Date of last PrEP dose	59. Date of last PrEP dose	60. Date of last PrEP dose
61. Date of last PrEP dose	62. Date of last PrEP dose	63. Date of last PrEP dose	64. Date of last PrEP dose
65. Date of last PrEP dose	66. Date of last PrEP dose	67. Date of last PrEP dose	68. Date of last PrEP dose
69. Date of last PrEP dose	70. Date of last PrEP dose	71. Date of last PrEP dose	72. Date of last PrEP dose
73. Date of last PrEP dose	74. Date of last PrEP dose	75. Date of last PrEP dose	76. Date of last PrEP dose
77. Date of last PrEP dose	78. Date of last PrEP dose	79. Date of last PrEP dose	80. Date of last PrEP dose
81. Date of last PrEP dose	82. Date of last PrEP dose	83. Date of last PrEP dose	84. Date of last PrEP dose
85. Date of last PrEP dose	86. Date of last PrEP dose	87. Date of last PrEP dose	88. Date of last PrEP dose
89. Date of last PrEP dose	90. Date of last PrEP dose	91. Date of last PrEP dose	92. Date of last PrEP dose
93. Date of last PrEP dose	94. Date of last PrEP dose	95. Date of last PrEP dose	96. Date of last PrEP dose
97. Date of last PrEP dose	98. Date of last PrEP dose	99. Date of last PrEP dose	100. Date of last PrEP dose

MSM Risk Index: Adapted from CDC PrEP Provider Supplement 2014. Originally published by Smith et al, J Acquir Immune Defic Syndr. 2012;60(4):421-427.

How old are you today?	If <18 years, score 0 If 18-28 years, score 8 If 29-40 years, score 5 If 41-48 years, score 2 If 49 years or more, score 0	<u>5</u>
In the last 6 months, how many men have you had sex with?	If >10 male partners, score 7 If 6-10 male partners, score 4 If 0-5 male partners, score 0	<u>0</u>
In the last 6 months, how many times did you have receptive anal sex (you were the bottom) with a man without a condom?	If 1 or more times, score 10 If 0 times, score 0	<u>10</u>
In the last 6 months, how many of your male sex partners were HIV- If >1 positive partner, score 8 positive?	If >1 positive partner, score 8 If 1 positive partner, score 4 If <1 positive partner, score 0	<u>0</u>
In the last 6 months, how many times did you have insertive anal sex (you were the top) without a condom with a man who was HIV- positive?	If 5 or more times, score 6 If 0 times, score 0	<u>0</u>
In the last 6 months, have you used methamphetamines such as crystal If yes, score 6 or speed?	If yes, score 6 If no, score 0	<u>0</u>
	Add down entries in right column to calculate total score	<u>15</u> TOTAL SCORE*

*** If score is 10 or greater, evaluate for intensive HIV prevention services including PrEP. If score is below 10, provide indicated standard HIV prevention services.**

*Lab Tests and Procedures
Required before Initiating PrEP*

- HIV Antigen/Antibody test
- Screening for signs/symptoms of acute HIV infection
- Renal function (CrCl must be ≥ 60)
- Hepatitis B serologies - (vaccinate if non immune)
- Hepatitis C serology

Starting PrEP

- Truvada once daily
- 3 month supply
- Insurance coverage
 - Pre- High Risk Sexual Behavior
 - Drug Manufacturer Co-Pay Card
- Takes 7-21 days to take effect

*Continuing PrEP
Therapy*

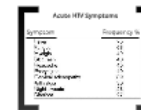
- Every 3 months
 - HIV testing and symptoms screening
 - Assess for side effects, adherence, and HIV acquisition behaviors
 - Provide support to increase adherence and decrease high risk behavior
 - Provide refill for no more than 90 days
- Every 6 months
 - Renal function (CrCl)
 - STI testing

Discontinuing PrEP

- Acquisition of HIV
- Change in sexual risk behavior
- Chronic non-adherence
- Patient choice

Prescribing PrEP

Lab Tests and Procedures Required before Initiating PrEP



Symptom	Duration %
Fatigue	20
Weight loss	20
Swollen lymph nodes	20
Joint pain	20
Headache	20
Flu-like symptoms	20
Low-grade fever	20
Other	20

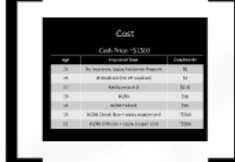
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- Screening for signs/symptoms of acute HIV infection
- Renal function (CrCl must be >60)
- Hepatitis B serologies- (vaccinate if non immune)
- Hepatitis C serology

Acute HIV Symptoms

Symptom	Frequency %
Fever	75
Fatigue	68
Myalgia	49
Skin rash	48
Headache	45
Pharyngitis	40
Cervical adenopathy	39
Arthralgia	30
Night sweats	28
Diarrhea	27

Starting PrEP

- Truvada once daily
- 3 month supply
- Insurance coverage
 - Dx: High Risk Sexual Behavior
 - Drug Manufacturer Co-Pay Card
- Takes 7-21 days to take effect



Cost	
Cash Price: \$1500	
Qty	Unit Price
1	\$1500.00
Total: \$1500.00	
Co-pay: \$0.00	
Total Paid: \$0.00	

Cost

Cash Price ~\$1500

Age	Insurance Type	Cost/month
23	No Insurance, Copay Assistance Program	\$0
25	IA Medicaid (NO PA required)	\$1
57	Medicare part D	\$6.35
29	BC/BS	\$30
42	BC/BS Federal	\$45
25	BC/BS Classic Blue + copay coupon card	~\$100
51	BC/BS UIChoice + copay coupon card	~\$200



Continuing PrEP Therapy

- Every 3 months
 - HIV testing and symptoms screening
 - Assess for side effects, adherence, and HIV acquisition behaviors
 - Provide support to increase adherence and decrease high risk behavior
 - Provide refill for no more than 90 days
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 - Renal function (CrCl)
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Discontinuing PrEP

- Acquisition of HIV
- Change in sexual risk behavior
- Chronic non-adherence
- Patient choice



Resources

- PrEPLine: 1-855-HIV-PREP
- CDC Guidelines
 - [cdc.gov/hiv/pdf/PrEPguidelines2014.pdf](https://www.cdc.gov/hiv/pdf/PrEPguidelines2014.pdf)
- UI LGBTQ Clinic website
 - uilgbtqclinic.com

Acknowledgments

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